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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,390	07/06/1999	PHILIP E. EGGERS	C-6-5	3789

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/347,390

Applicant(s)

EGGERS ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,9,12-14,18-22,25 and 27-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, 10, 11, 15-17, 23, 24, 26 and 41-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2005 has been entered.

It is noted that applicant's have "withdrawn" claim 25. It is not clear what is the intent of withdrawing the claim. The examiner assumes applicant meant to cancel the claim, and is proceeding under that notion. Clarification of this issue is respectfully requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6, 11, 23, 24, 26 and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al (5,389,096) in view of the teachings of Swartz et al (5,902,289) Mulier et al (5,431,649) and Nardella (5,334,193).

Aita et al disclose a laser catheter device for performing PMR procedures. The catheter is advanced into the ventricle of a heart and then used to form channels within the heart wall. Aita et al fail to specifically disclose the use of electrosurgical energy as

the treatment energy. The particular channel size (applicant's claim 11) is deemed to be an obvious consideration for one of ordinary skill in the art and commensurate in size with the catheter used by Aita et al. Further, one of ordinary skill in the art would obviously, if not inherently, terminate the delivery of energy when the wall of the heart was penetrated to prevent the ablation of non-targeted tissue.

Swartz et al disclose another cardiac treatment catheter apparatus. In particular, Swartz et al teach that it is generally known in the art to substitute various well-known energy modalities in a cardiac ablation catheter. In particular, Swartz et al teach that it is known to use either laser or RF energy for ablating cardiac tissue (col. 11, lines 3-12). However, Swartz et al fail to disclose the use of a conductive fluid to enhance the electrosurgical procedure.

Mulier et al disclose a cardiac ablation catheter that includes RF electrodes for ablating tissue. In particular, Mulier et al disclose the specific advantages of providing a conductive fluid to tissue during RF ablation to enhance the ablation procedure and cool tissue. (see Abstract and col. 2, lines 8+). Mulier et al fail to specifically disclose the use of a saline solution, or the specific voltage levels used to ablate tissue.

Nardella disclose a device analogous to the Mulier et al device. It includes a catheter having a helical electrode for ablating tissue. Nardella also disclose providing a fluid to the electrode/tissue interface for cooling, and specifically teach that the fluid may be saline (col. 4, line 51). Nardella also specifically teach the use of RF energy for ablating tissue having voltage levels within the range set forth by the applicant (col. 5, lines 60-64). The examiner maintains that there is sufficient motivation to provide the

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combination of the Mulier et al and Nardella teachings to the Aita system. Such a system that provides for the electrode structure for treating tissue in the vicinity of a saline solution with the appropriate voltage levels would inherently yield the same results (i.e. inducing the discharge of energetic electrons and photons).

To have provided the Aita et al system with an RF energy catheter, in lieu of the laser energy catheter, for performing the TMR procedure would have been an obvious modification for one of ordinary skill in the art, particularly since Swartz et al teach the known substitutability of these two modalities in treating cardiac tissue. To have further provided a conductive solution to the tissue site during the ablation procedure to enhance tissue ablation would have been an obvious consideration for one of ordinary skill in the art in view of the teachings of Mulier et al and Nardella.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al ('096), Swartz et al ('289), Nardella ('334) and Mulier et al ('649) as applied to the claims above, and further in view of the teaching of Rudko (5,125,924).

The combination of the Swartz et al and Mulier et al teachings with the Aita et al system has been addressed previously. Neither Swartz et al nor Aita et al specifically disclose the firing of ablative energy in concert with a monitored EKG cycle.

Rudko et al disclose a laser heart ablation catheter. In particular, Rudko et al teach that it is advantageous to monitor EKG activity and synchronize the delivery of ablative energy with specific intervals of the EKG cycle to more safely treat the heart

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tissue. That is, ablative energy is fired when the heart is in its most stable state to prevent errant firing of ablative energy on the moving heart.

To have provided the Aita et al system, as modified by the teachings of Swartz et al and Mulier et al, with a means to synchronize the delivery of ablative energy during calm periods of the heart beat cycle to more accurately deliver the ablative energy would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Rudko.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-8, 10, 11, 15-17, 23, 24, 26 and 41-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 5,873,855. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 1-3, 6-8, 10, 11, 15-17, 23, 24, 26 and 41-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 5,683,366. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 1-3, 6-8, 10, 11, 15-17 and 23-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-104 of U.S. Patent No. 5,697,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 1-3, 6-8, 10, 11, 15-17, 23, 24, 26 and 41-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-56 of U.S. Patent No. 5,697,882. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 1-3, 6-8, 10, 11, 15-17, 23, 24, 26 and 41-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,032,674. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 1-3, 6-8, 10, 11, 15-17, 23, 24, 26 and 41-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/054,660. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

It is noted that applicant has indicated that a terminal disclaimer has been filed with the November 5, 2005 response (see page 11). However, no terminal disclaimer has been found in the response papers and the response transmittal letter does not indicate that a terminal disclaimer has been included.

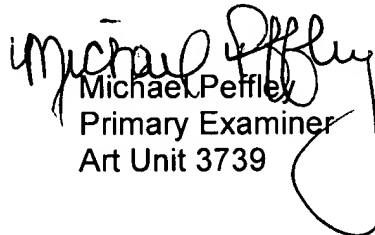
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
February 14, 2006